

**MARKED VERSION OF THE CLAIMS**

1. (Original) A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a Clostridial neurotoxin to a mammary gland, thereby treating a mammary gland disorder.
2. (Original) The method of claim 1, wherein the Clostridial neurotoxin is a botulinum toxin.
3. (Original) The method of claim 2, wherein the botulinum toxin is administered in an amount of between about  $10^{-2}$  U/kg and about 200 U/kg.
4. (Original) The method of claim 2, wherein the botulinum toxin is administered in an amount of between about  $10^{-1}$  U/kg and about 35 U/kg.
5. (Original) The method of claim 2, wherein the botulinum toxin is selected from the group consisting of botulinum toxins types A, B, C, D, E, F and G.
6. (Original) The method of claim 2, wherein the botulinum toxin is botulinum toxin type A.
7. (Original) The method of claim 2, wherein local administration of the botulinum toxin is carried out by implantation of a botulinum toxin implant into or onto the mammary gland.
8. (Original) The method of claim 1, wherein the mammary gland disorder is selected from the group consisting of precancerous breast tissue and breast cancer.

9. (Original) The method of claim 1, wherein the mammary gland disorder is cystic breast disease.

10. (Original) The method of claim 2, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the mammary gland.

11. (Currently amended) A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a botulinum toxin type A to a mammary gland of a human patient, thereby treating a mammary gland disorder by reducing a secretion from the mammary gland. ~~and treating a mammary gland disorder.~~

12. (Currently amended) A method for treating a mammary gland disorder, the method comprising the step of local administration of a botulinum toxin to a mammary gland or to the vicinity of a precancerous breast tissue, thereby causing a reduction in the size and/or activity of a ~~hyperplastic~~ hyperplastic, hypertonic or neoplastic mammary gland tissue.

13. (Currently amended) The method of claim 12, wherein the diameter of the ~~hyperplastic~~ hyperplastic, hypertonic or neoplastic mammary gland tissue is reduced by between about 20% and about 100% subsequent to the local administration of the botulinum toxin.

14. (Currently amended) A method for treating a mammary gland disorder, the method comprising the step of local administration of a therapeutic amount of a botulinum toxin to a ~~hyperplastic~~ hyperplastic, hypertonic or neoplastic mammary gland tissue, thereby causing a reduction in the diameter of the ~~hyperplastic~~ hyperplastic, hypertonic or neoplastic mammary gland tissue of between about 20% and about 100%.

15. (Original) A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of a botulinum toxin to a hyperplasic or hypertonic mammary gland tissue, thereby reducing a secretion from the hyperplasic or hypertonic mammary gland tissue and preventing the hyperplasic or hypertonic mammary gland tissue from developing into a neoplasm.

16. (Original) The method of claim 15, wherein the botulinum toxin is administered in an amount of between about  $10^{-3}$  U/kg and about 2,000 U/kg.

17. (Original) The method of claim 16, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

18. (Original) The method of claim 15, wherein the botulinum toxin is botulinum toxin type A.

19. (Original) The method of claim 15, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the hyperplasic or hypertonic mammary gland tissue.

20. (Original) A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of a therapeutic amount of a botulinum toxin type A to the precancerous hyperplasic or hypertonic mammary gland tissue of a human patient, thereby preventing development of a mammary gland neoplasm.

21-31. (Cancelled)

32. (Currently amended) A method for preventing development of a mammary gland carcinoma, the method comprising the step of local

administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a botulinum toxin type A to a ~~hyperplastic~~ hyperplasic breast tissue of a human patient, wherein the ~~hyperplastic~~ hyperplasic breast tissue comprises a substrate for the botulinum toxin selected from the group of vesicle membrane docking proteins consisting of a 25 kiloDalton synaptosomal associated protein (SNAP-25), synaptobrevin and syntaxin, and wherein the botulinum toxin acts upon the substrate to reduce a secretion from the hyperplasic breast tissue.

33. (Original) A method for treating a mammary gland disorder selected from the group consisting of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, and proliferative breast disease, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a Clostridial neurotoxin to a mammary gland, thereby treating the mammary gland disorder.

## CLEAN VERSION OF THE CLAIMS

1. A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a Clostridial neurotoxin to a mammary gland, thereby treating a mammary gland disorder.
2. The method of claim 1, wherein the Clostridial neurotoxin is a botulinum toxin.
3. The method of claim 2, wherein the botulinum toxin is administered in an amount of between about  $10^{-2}$  U/kg and about 200 U/kg.
4. The method of claim 2, wherein the botulinum toxin is administered in an amount of between about  $10^{-1}$  U/kg and about 35 U/kg.
5. The method of claim 2, wherein the botulinum toxin is selected from the group consisting of botulinum toxins types A, B, C, D, E, F and G.
6. The method of claim 2, wherein the botulinum toxin is botulinum toxin type A.
7. The method of claim 2, wherein local administration of the botulinum toxin is carried out by implantation of a botulinum toxin implant into or onto the mammary gland.
8. The method of claim 1, wherein the mammary gland disorder is selected from the group consisting of precancerous breast tissue and breast cancer.
9. The method of claim 1, wherein the mammary gland disorder is cystic breast disease.

10. The method of claim 2, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the mammary gland.

11. (Currently amended) A method for treating a mammary gland disorder, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a botulinum toxin type A to a mammary gland of a human patient, thereby treating a mammary gland disorder by reducing a secretion from the mammary gland.

12. A method for treating a mammary gland disorder, the method comprising the step of local administration of a botulinum toxin to a mammary gland or to the vicinity of a precancerous breast tissue, thereby causing a reduction in the size and/or activity of a hyperplastic, hypertonic or neoplastic mammary gland tissue.

13. The method of claim 12, wherein the diameter of the hyperplastic, hypertonic or neoplastic mammary gland tissue is reduced by between about 20% and about 100% subsequent to the local administration of the botulinum toxin.

14. A method for treating a mammary gland disorder, the method comprising the step of local administration of a therapeutic amount of a botulinum toxin to a hyperplastic, hypertonic or neoplastic mammary gland tissue, thereby causing a reduction in the diameter of the hyperplastic, hypertonic or neoplastic mammary gland tissue of between about 20% and about 100%.

15. A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of a botulinum toxin to a hyperplastic or hypertonic mammary gland tissue, thereby reducing a secretion from the hyperplastic or hypertonic mammary gland tissue and preventing the

hyperplastic or hypertonic mammary gland tissue from developing into a neoplasm.

16. The method of claim 15, wherein the botulinum toxin is administered in an amount of between about  $10^{-3}$  U/kg and about 2,000 U/kg.

17. The method of claim 16, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

18. The method of claim 15, wherein the botulinum toxin is botulinum toxin type A.

19. The method of claim 15, wherein the botulinum toxin is locally administered by direct injection of the botulinum toxin into the hyperplastic or hypertonic mammary gland tissue.

20. A method for preventing development of a mammary gland neoplasm, the method comprising the step of local administration of a therapeutic amount of a botulinum toxin type A to the precancerous hyperplastic or hypertonic mammary gland tissue of a human patient, thereby preventing development of a mammary gland neoplasm.

32. A method for preventing development of a mammary gland carcinoma, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a botulinum toxin type A to a hyperplastic breast tissue of a human patient, wherein the hyperplastic breast tissue comprises a substrate for the botulinum toxin selected from the group of vesicle membrane docking proteins consisting of a 25 kiloDalton synaptosomal associated protein (SNAP-25), synaptobrevin and syntaxin, and wherein the botulinum toxin acts upon the substrate to reduce a secretion from the hyperplastic breast tissue.

33. A method for treating a mammary gland disorder selected from the group consisting of a breast cyst, sclerosing adenosis, duct papilloma, fibroadenoma, blunt duct adenosis, and proliferative breast disease, the method comprising the step of local administration of between about  $10^{-3}$  U/kg and about 2000 U/kg of a Clostridial neurotoxin to a mammary gland, thereby treating the mammary gland disorder.